



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

March 27, 2015

Futrex, Inc.
Ms. Carole Rosenthal, President
130 Western Maryland Parkway
Hagerstown, MD 21740

Re: K143108
Trade/Device Name: HealthGuard-15
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN, MNW
Dated: February 11, 2015
Received: February 18, 2015

Dear Ms. Rosenthal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

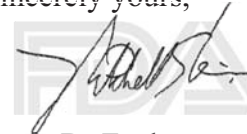
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a large, faint, light-gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143108

Device Name: HealthGuard-15

Indications For Use:

The HealthGuard-15 is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs. It is not for use in medical facilities such as hospitals or doctor's offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
(Per 21 CFR 807.92)

I. Applicant

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130 Western Maryland Parkway
Hagerstown, Maryland 21740 USA

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II. Date Preparation

This 510(k) Summary was prepared on October 27, 2014

III. Medical Device

Trade Name: HealthGuard-15
Common Name: Non-invasive Blood Pressure and Body Composition
Measurement System
Classification Number: 21 CFR 870.1130
Classification: Class II
Panel: Circulatory System Device Panel
Product Code: DXN (for Blood Pressure)
MNW (for Body Composition Analysis)

IV. Predicate Devices

- (1) Health Check Kiosk -- (K063008)
- (2) Omron HEM-7200-Z (BP742) -- (K121932)
- (3) FUTREX-6100/XL -- (K963271)

V. Intended Use of the Device

The HealthGuard-15 ("HG-15") is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs.

It is not for use in medical facilities such as hospitals or doctors' offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.

VI. Description of the Device

The HealthGuard-15 is a portable health kiosk that provides a means for measuring and tracking an individual's systolic and diastolic blood pressure, heart rate, percent body fat and weight. The HG-15 integrates two FDA market cleared devices ---- *the Omron HEM-7200-Z [BP742] (K121932) for measurement of blood pressure and heart rate, and the FUTREX-6100/XL (K963271) for the estimation of the percent body fat ---* into a health kiosk with similar performance as the Health Check Kiosk (K063008).

The HG-15 kiosk can typically be installed in corporate offices, lunch rooms or other community places so that employees can be measured as part of a corporate wellness program to track changes over time. It is not for use in hospitals or in other health care facilities.

The HG-15 is delivered without the necessary PC computer. The client supplies the computer and Futrex supplies not only the HealthGuard-15 "kiosk" but also supplies the software that will be driven by the client's computer.

In addition to making the measurements, the HealthGuard-15 also provides the recognized norms for systolic and diastolic blood pressure and weight. It provides a direct comparison of the user's measurements to these established norms, thereby providing education and motivation to the user. The computer/s monitor also warns the user not to start any exercise or diet program without first discussing it with their healthcare professional.

VII. Technical Considerations

The HealthGuard-15 measures systolic and diastolic blood pressure using the standard oscillometric measurement method. The device includes a unique patented cuff mechanism suitable upper arm measurements of arm circumferences 9" to 13". When the arm is inserted in the cuff, the cuff automatically wraps around the arm similar to the way it is done in a doctor's office. The cuff is then inflated before it is gradually deflated through a series of controlled deflation steps in accordance with specification. The blood pressure measurement is controlled by the client's

computer using the Futrex supplied software. The only exception to this software control is the hardware “ABORT” red pushbutton that has override authority.

VIII. Substantial Equivalence

The HealthGuard-15 is substantially equivalent to these predicate devices:

- As a multi-measurement kiosk: The Health Check Kiosk (K063008)
- For blood pressure measurements: The Omron HEM-7200-Z (BP742) (K121932)
- For body fat measurements: the FUTREX-6100/XL (K963271)

Tables comparing various aspects of the HealthGuard-15 to its predicate devices start on the next page:

Table 5.1 - Comparing the HealthGuard Device to the Predicate Kiosk Device

	Predicate Device	HealthGuard Device	
	Xperex, Inc. Health Check Kiosk (K063008)	Model-15	Comment
Indications for Use	The Health Check is intended to be used by the general public so that a user can measure health parameters such as weight, body fat , blood pressure and pulse rate in public places and/or corporate environments. It is not for diagnostic use.	The HealthGuard-15 is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs. It is not for use in medical facilities such as hospitals or doctors' offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.	Similar
Intended Population	General Public	Health/Fitness Clubs	Similar
Hardware Design	Xperex Health Check Kiosk uses a built-in computer to control blood pressure, pulse rate and percent body fat measurements. A STOP pushbutton cancels the blood pressure measurement.	HealthGuard uses the PC computer to control the device. A STOP push button cancels the blood pressure measurement.	Similar
Software Design	Xperex Health Check Kiosk uses software as an automated system for measuring blood pressure and pulse rate. It is completely automatic, and measures blood pressure by the oscillometric method. The user is guided by a series of interactive screens and voice instructions.	The HealthGuard-15 software controls all measurements that the device makes. It is completely automatic and measures blood pressure using the oscillometric method. The user is guided by a series of interactive screens.	Similar
Materials	Latex free polyester thread for cuff. (The rest of their materials are unknown.)	Metal housing, ABS plastic, Nylon material used in cuff cover, and latex free thread in cuff cover.	Similar
Cleaning Materials	Non-sterile; cleaning and disinfecting instructions are provided.	Non-sterile; cleaning and disinfecting instructions are provided.	Identical
Electromagnetic Compatibility	Unknown	Meets IEC 60601-1-2	-

Table 5.1 (Continued)

Components	Blood Pressure, Body Fat, Pulse Rate and Weight	Blood Pressure, Body Fat, Pulse Rate and Weight	Identical
Blood Pressure	Oscillometric method. The user is guided by a series of interactive screens and voice instructions.	Oscillometric method. The user is guided by a series of interactive screens.	Similar
Body Fat Technology	Near-IR	Near-IR	Identical
User Interaction	Interactive screens and voice instructions	Interactive screens	Similar

Measurement of Blood Pressure – The predicate blood pressure measurement device is the Omron HEM-7200-Z [BP742] (K121932) - - - hereinafter called the “Omron BP742.” The HealthGuard-15’s blood pressure measurement is accomplished by building the Omron BP742 into the HG-15. The only modifications made to the built-in BP742 are:

- The plastic exterior covers are removed.
- The pushbutton that starts the measurement has been replaced by a computer command signal.
- The inflation bladder’s cloth cover was replaced with a more durable Nylon cloth cover.

Comprehensive bench performance tests were performed that proved that these minor changes did not affect the accuracy or precision of the systolic and diastolic blood pressure measurements and the heart rate measurement.

Table 5.2 compares the specifications of the predicate Omron BP742 with the device as installed in the HealthGuard-15.

Table 5.2 – Blood Pressure Measurement Device Comparison

	Omron Hem-7200-Z [BP742] (K121932)	HealthGuard-15	Comment
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The HealthGuard-15 is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs. It is not for use in medical facilities such as hospitals or doctors' offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.	Similar
Patient Population	Adult	Adult	Identical
Environment of Use	Home	Health & fitness centers	Similar
Prescriptive	OTC	OTC	Identical
Patient Connection	Yes via cuff	Yes via cuff	Identical
Technology	Oscillometric	Oscillometric	Identical
Measurement range	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Identical
Accuracy or pressure indicator	+/-3 mmHg or 2% of reading	+/-3 mmHg or 2% of reading	Identical
Accuracy Pulse Rate	+/-5%	+/-5%	Identical
Inflation Method	DC rolling pump	DC rolling pump	Identical
Deflation Method	Dynamic linear deflation	Dynamic linear deflation	Identical
Display Type	Graphical	Graphical	Similar
Auscultatory	No	No	Identical
Power Source	AA battery or AC adapter	Rechargeable Battery	Similar
Operating Conditions	Temperature: 10° to 40° C Humidity: 15 to 90% RH	Temperature: 10° to 40° C Humidity: 15 to 90% RH	Identical
Storage Conditions	Temperature: -20° to 60° C Humidity 10 to 95% RH	Temperature: -20° to 60° C Humidity 10 to 95% RH	Identical

Measurement of Percent Body Fat – The predicate body fat measurement device is the FUTREX-6100/XL (K963271). The HealthGuard-15's percent body fat measurement is accomplished by building the FUTREX-6100/XL into the HG-15. The only modifications made to the FUTREX-6100/XL are:

- The measurement site is on the triceps area at a fixed distance from the elbow instead of at the center of the biceps.
- Measurement is always on the left arm instead of always being done on the dominant arm.
- The pushbutton that starts the measurement has been replaced by a computer command signal.

Comprehensive bench performance tests were performed that proved these changes did not affect the accuracy or precision of the percent body fat measurements.

Table 5.3 compares the specifications of the unmodified predicate FUTREX-6100/XL with the device as installed in the HealthGuard-15.

Table 5-3 – Percent Body Fat Device Measurement Comparison

	Predicate Device FUTREX-6100/XL (K9632710)	HealthGuard-15	Comment
Indications for Use	The FUTREX-6100/XL is to be used to estimate the percent body fat in adult humans between the ages of 18-85. It has not been validated for subjects using diuretics or estrogen replacement therapy.	The HealthGuard-15 is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs. It is not for use in medical facilities such as hospitals or doctors' offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.	Similar.
Product Code	MNW	MNW	Identical
Patient Population	Adults	Adults	Identical
Environment for Use	Not for diagnostic use	Not for diagnostic use	Identical
Prescriptive	OTC	OTC	Identical
Patient Connection	Yes via Cuff	Yes via Cuff	Identical
Technology	Near-IR	Near-IR	Identical
Prime Wavelength	940 nm	940 nm	Identical
Measurement Site	On biceps of dominant arm	On triceps of left arm	Similar (see Note 2)
Measurement Time	2 seconds approximately	2 seconds approximately	Identical
Limitations	Measurement site must not be covered with clothing	Measurement site must not be covered with clothing	Identical
Data Provided to the User	% body fat, BMI, BMR, % lean, % water.	% body fat, BMI, BMR, % lean, % water.	Identical
Measurement Range	2 – 45%	2 – 45%	Identical
Accuracy	Equal to official method of hydrostatic weighing	Equal to official method of hydrostatic weighing	Identical
Precision	0.3%	0.3%	Identical
Power Source	Batteries or an AC Adapter	12 V Rechargeable Battery	Similar
Operating Conditions	Temperature: 10° to 40° C Humidity: 15 to 90% RH	Temperature: 10° to 40° C Humidity: 15 to 90% RH	Identical
Storage Conditions	Temperature: -20° to 60° C Humidity 10 to 95% RH	Temperature: -20° to 60° C Humidity 10 to 95% RH	Identical

NOTE 2 – Performance bench testing has been performed to demonstrate that this difference does not affect the accuracy of measurement.

IX. Testing

The HealthGuard-15 has been subjected to bench testing to ascertain measurement precision and accuracy compared to its predicate devices. This bench performance testing demonstrated that the HealthGuard-15 measurements are substantially equivalent to the predicate devices.

Moreover, testing by an independent laboratory has shown that the HealthGuard-15 also satisfies the EMC requirements for medical electrical equipment. Similarly, the HealthGuard-15 satisfied the safety requirements for electrical medical equipment.

X. Contraindications

There are no known contraindications.

XI. Differences Between Other Legally Marketed Predicate Devices

The HG-15, as shown in the previous three tables, has only minor differences to its predicate devices. Bench testing has been performed that proved that these minor differences do not diminish the HG-15's safety or effectiveness.

XII. Indications

The indications for use are identical

XIII. Design and Technology – The HG-15 has equivalent design and features as its predicate devices, and uses essentially the identical technology as its predicate devices.**XIV. Performance and Specifications** – The HG-15 has equivalent specifications of performance as its predicate devices.**XV. Compliance with standards** – The HG-15 are in compliance with the following Standards:

- ISO 14971
- ANSI/AAMI SP10
- BS/EN 60601-1

XVI. Materials

The patient contact material of the HG-15 (the cuffs) has been FDA market cleared in other 510(k) submissions as described in **Section 15 – Biocompatibility**. Materials are detailed in Section 15 as well.

XVII. Environment of Use

The HG-15 is intended for use in business locations

XVIII. Patient Population

The HG-15 and its predicate devices are for populations 18 years and older.

XIX. Performance Testing

We have performed bench tests and found that the HG-15 met all requirements, specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Testing for compliance to IEC 60601-1
- Testing for compliance o IEC 60601-2
- Testing for compliance to AAMI SP10
- Comparative Testing to the Predicate

XX. Conclusion

Futrex maintains that the HealthGuard-15 is substantially equivalent to the predicate devices (listed in Item IV above) in indications for use, patient population, environment for use, technology characterizes, specifications/performance and compliance with international standards.